IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, and THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; *ex rel.* JOHN CRAGAR Plaintiff and Relator v. BIOGEN IDEC, and ELAN CORPORATION, PLC and ELAN PHARMACEUTICALS, INC. Defendants.	) CIVIL ACTION NO. 1:11CV13 **FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

FIRST AMENDED FALSE CLAIMS ACT COMPLAINT

INTRODUCTION

1. JOHN CRAGAR ("Relator") brings this action on behalf of the UNITED STATES OF AMERICA against BIOGEN IDEC (hereinafter referred to as "BIOGEN"), ELAN CORPORATION, PLC (hereinafter referred to as "ELAN PLC") and ELAN PHARMACEUTICALS, INC. (hereinafter referred to as "ELAN"), collectively referred to as

"Defendants," for treble damages and civil penalties arising from Defendants' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA").

2. This action is also brought under the respective *qui tam* provisions of False Claims Acts (or similarly named) on behalf of the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. These states, together with the United States, are hereafter collectively referred to as the Government.

3. The violations arise out of requests for payment by Medicare, Medicaid, TRICARE, and possibly other federally-funded government healthcare programs (hereinafter referred to as "Government Healthcare Programs").

4. Defendant Biogen Idec is itself the result of a 2003 merger of Massachusetts-based Biogen Inc., and San Diego, California-based Idec Pharmaceuticals. Defendant Biogen Idec markets two blockbuster drugs, multiple sclerosis drug Avonex and cancer drug Rituxan, and also markets multiple sclerosis drug Tysabri. Its principal place of business is at 133 Boston Post Road, Weston, MA 02493. Biogen is traded on NASDAQ under the symbol "BIIB." Biogen conducts business in every state within the United States.

5. Defendant Elan Corporation, PLC ("ELAN, PLC") is a publicly-traded neuroscience-based biotechnology company. ELAN, PLC focuses on the discovery, development, manufacturing, and marketing of therapies in the areas of neurology, autoimmune

diseases, and severe pain. The corporation is headquartered in Dublin, Ireland, with operations in the United States and several other countries.

6. Defendant Elan Pharmaceuticals, Inc. ("ELAN") is ELAN PLC's subsidiary. Its principal place of business is at 7475 Lusk Boulevard, San Diego, California 92121. ELAN is traded on the New York Stock Exchange under the symbol "ELN." ELAN, PLC and its U.S. subsidiary ELAN conduct business in every state within the United States.

7. This case involves a massive patient marketing scheme that steered MS patients to known prescribers of Defendants' products by directly targeting patients with substantial cash payments, lavish dinner meetings with select physicians, and misleading information about MS products. Defendants cornered the MS therapy market by also strategically seeking out and paying kickbacks to the highest-prescribing MS specialists in the country, to induce providers to use its MS products.

8. Relator was employed by BIOGEN as an Account Business Manager (ABM), responsible for improving Biogen's sales of its multiple sclerosis injectibles, Avonex and Tysabri, in the Houston and Galveston markets. With nearly two decades of pharmaceutical sales experience, Relator was specifically tasked with targeting high-prescribing neurological specialists, including neurologists and pediatric neurologists. Relator was terminated in November of 2010.

9. Relator has complied with all procedural requirements of the laws under which this case is brought.

10. Relator is informed and believes that the pervasive kickbacks and false claims described herein began at least six years ago, and continue to date.

FEDERAL JURISDICTION AND VENUE

11. The acts proscribed by 31 U.S.C. § 3729 *et seq.* and complained of herein occurred in part in the Western District of Virginia, and Defendants do business in the Western District of Virginia. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a), as well as under 28 U.S.C. § 1345. This Court has jurisdiction over this case for the claims brought on behalf of the states (referenced in paragraph 2) pursuant to 31 U.S.C. § 3732(b), inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claim brought on behalf of the United States.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendants transact business in this District.

13. The facts and circumstances which give rise to Defendants' violation of the False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

14. Relator is the original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

15. Relator brings this action based on his direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. § 3730(e)(4), and Relator is an original source of the facts alleged in this Complaint.

16. At all times, Defendants acted through its agents and employees, and the acts of Defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of Defendants.

THE REGULATORY ENVIRONMENT

17. Under the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded healthcare program, including Medicare, Medicaid, and TRICARE.

18. The Anti-Kickback Act is designed to ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

19. Every federally-funded healthcare program requires all providers and suppliers to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of healthcare services in the United States.

20. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits, or to gain favor for its product over the product of any competitor.

21. A violation of the Anti-kickback Act is a violation of the False Claims Act. The Federal False Claims Act provides, in pertinent part that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States

> Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;
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> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

22. The United States Food, Drug and Cosmetic Act (FDCA) establishes the framework for regulation of the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. When the United States Food and Drug Administration ("FDA") approves a drug, it approves the drug only for the particular use for which it was tested.

23. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from *marketing or promoting* a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

24. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use, also known as "misbranding," constitutes unlawful promotional advertising of the drug, violates the FDCA, and can also serve as the basis for an FCA violation.

25. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. For example, the FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (B) manufacturer support for Continuing Medical Education ("CME") programs and "speaker" programs, that focus on off-label uses.

26. With regard to the first practice—disseminating written information—the FDCA allows a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; and has provided the materials to the FDA before dissemination. The materials must be submitted in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

INFORMATION ABOUT THE DRUGS AND THE DISEASE

Multiple Sclerosis

27. MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active relapsing MS experience an uneven pattern of disease

progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning.

Avonex

28. Avonex was FDA-approved in 1996 and is indicated "for the treatment of patients with relapsing forms of multiple sclerosis (MS) to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS."

29. Annual U.S. sales now exceed $1.3 billion, and it is the most prescribed treatment for relapsing forms of MS.

Tysabri

30. Tysabri was FDA-approved in 2004. The profits on the drug are split between Biogen Idec and ELAN. According to Tysabri's FDA-approved product labeling (PI):

> TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations . . . . Because TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability, TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies.

31. Tysabri was withdrawn from the market in February 2005, after it was found that three patients taking the drug developed progressive multifocal leukoencephalopathy, or PML, a rare but potentially fatal brain disease. Defendants issued a press release in April 2005, indicating that a third patient receiving Tysabri had been diagnosed. The latest diagnosis was in

a patient participating in a trial of Tysabri as a treatment for Crohn's disease, who died in December 2003.

32. In July 2006, Tysabri was reintroduced to the market with a boxed warning for PML and the TOUCH restricted distribution program. The FDA has recommended that Tysabri should be used as a stand-alone treatment and not combined with other drugs that suppress the immune system. Previously, Tysabri was prescribed along with Avonex. Annual U.S. sales now exceed $500 million.

Tysabri Black Box Warning

33. The PI contains the following boxed warning for PML (in pertinent part) (emphasis added):

> TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Cases of PML have been reported in patients taking TYSABRI who were recently or concomitantly treated with immunomodulators or immunosuppressants, as well as in patients receiving TYSABRI as monotherapy…
>
> Because of the risk of PML, TYSABRI is available only through a special restricted distribution program called the TOUCH™ Prescribing Program . . .

34. Safety concerns continue to haunt the drug. As reported in Reuter's on 1/21/11, Biogen acknowledged that 6 new cases of PML occurred in December, bringing the current total to 85 reported cases. Of the 85 cases of PML reported, 16 patients have died, while 69 are still alive with varying degrees of disability.

Competitor Drugs

35. AVONEX and TYSABRI both compete primarily with six other products. Each of these medications in some way alters the course of MS. With the exception of the oral product Gilenya, each competitor medication is available in injectable form only. In general, the medications reduce the frequency of exacerbations of MS, reduce the amount of activity seen on MRI scanning, and may slow progression of MS.

- GILENYA, an oral MS drug marketed by Novartis AG, was FDA approved in September 2010.
- BETASERON (interferon-beta-1b), which is marketed by Bayer HealthCare Pharmaceuticals.
- EXTAVIA, a branded version of interferon beta-1b marketed by Novartis AG, was launched in the U.S. in October 2009.
- COPAXONE (glatiramer acetae), which is marketed by Teva Pharmaceutical Industries Ltd.
- REBIF (interferon-beta-1a), which is co-promoted by EMD Serono, a subsidiary of Merck Serono and Pfizer Inc.
- NOVANTRONE (mitoxantrone), which is marketed by OSI Pharmaceuticals.

GOVERNMENT HEALTHCARE PROGRAMS

36. Government Healthcare Programs cover prescription drugs. They include, but are not limited to, the following programs.

The Medicaid Program

37. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to

low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. *See* 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan ..." *See* 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

38. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

39. Whether an FDA-approved drug is listed for a particular indication (i.e., use) determines whether a prescription for that use may be reimbursed under Medicaid.

40. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6).

The Medicare Program

41. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

42. The Medicare Prescription Drug benefit (Part D) covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k) (as described above). Part A and Part B of the Medicare Program also cover prescription drugs that are "reasonable and necessary."

43. In or about May 2002, Medicare announced it would cover Biogen, Inc.'s (Cambridge MA) injectable multiple-sclerosis drug Avonex, but not three other medications commonly prescribed to stave off symptoms of the disease. In a memo (effective August 2002) sent to the private companies that serve as regional Medicare carriers, the Centers for Medicare and Medicaid Services said an injectable drug should be covered if Medicare beneficiaries self-administer it less than 50% of the time.

Reimbursement Under Other Federal Healthcare programs

44. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities.

45. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

46. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

47. Coverage of off-label drug use under these programs is similar to coverage under the Medicare and Medicaid programs. *See, e.g.,* TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

ILLEGAL MARKETING DIRECT TO PATIENTS

48. Defendant Biogen devised a massive patient marketing scheme, which steered MS patients to known prescribers of Defendants' products and directly targeted patients with substantial cash payments, lavish dinners, and misleading information. Patient marketing was a

driving force behind the success of Avonex and Tysabri, making up an astounding 30% plus, of Defendant Biogen's marketing budget.

49. Over the last five years, Defendant Biogen has shelled out over $500 million to patients and patient programs, including tens of millions of dollars in building an elaborate "patient services" program, complete with a high-tech concierge call center, a comprehensive patient tracking system, well-orchestrated live events for MS patients, and an online patient portal, akin to Facebook.

Sophisticated Patient Database and Call Center

50. ABMs emphasize that Biogen would find a way to make sure that all patients received the prescribed products, regardless of the patient's financial standing. But ABMs were to stress that this premium-level of service was only available when the prescribing physician filled out an "RSVP Form," "ASAP Form," or "Start Form." Provided in lieu of prescriptions, these forms supplied Defendant Biogen with detailed patient information, including contact information and disease state. These forms were sent directly to Biogen's patient call center in Raleigh, North Carolina, where the information was entered into a highly sophisticated database.

51. Once Biogen received the ASAP Forms at its Raleigh call center, a "case manager" would triage the patients by walking them through all of the financial options for payment, including Medicare, Medicaid, a special MS fund, and, when all else failed, a dedicated Biogen fund. Management repeatedly bragged to the sales force that this triage approach was able to funnel most of the prescriptions to Government Healthcare Programs.

52. Defendant Biogen would regularly send promotional materials to the patients via mail, email, fax, and phone. This information would tout the benefits of staying on their products and would invite the patients to high-end informational events, where the patients would receive meals, promotional materials, free gifts, and hear from "celebrity MS patients." Defendant Biogen would also used the patients' contact information to match them with mentors who were Biogen patients, who were paid to call potential, current and former Biogen patients. These mentors would receive up to $300 per phone call.

53. Defendant Biogen interjected itself between the physician and the patient. Biogen devised a subversive effort to encourage patients to return to Tysabri, even when the patients' physicians have decided to suspend the patients' treatment. This is particularly troubling given Tysabri's black box warning, which explicitly states, "most cases of PML were in patients who received more than one year of treatment." In the face of these life-threatening concerns, Defendant Biogen nevertheless aggressively promoted the extended usage of Tysabri to patients. Indeed, when Tysabri was permitted back on the market, the FDA required Biogen to implement a patient tracking system, so it could monitor adverse events. Biogen tapped the sales force into this tracking system, so the ABMs could immediately follow-up with any new or discontinued patients.

54. ABMs worked closely with "Patient Services" to ensure that Defendant Biogen catered to all of the patients' needs. If they expressed an interest in stopping treatment, Patient Services would route the call to trained Patient Mentors who would dissuade the patients from venturing elsewhere. If ability-to-pay questions were raised, Patient Services would send the caller to a government payor reimbursement specialist. If the patients needed monetary

encouragement to continue using Biogen products, Patient Services could add them to the queue of approved Patient Mentors.

Patient Education Programs (PEPs)

55. In addition, Defendant Biogen used the patient marketing database to repeatedly invite potential, current, and former Biogen patients to attend company-organized MS patient pep rallies. These so-called "Patient Education Programs," or "PEPs," were a major component of Defendant Biogen's patient kickback schemes. Each ABM was ordered to organize as many PEPs as possible, with the result that nearly 1,000 PEPs were held within the past year, with an average of 100 MS patients in attendance at each event. As Biogen spent between $7,500 and $10,000 on each PEP, Relator estimates that an astounding $7.5–10 million was spent yearly on this patient program alone.

56. To further drive up attendance, Defendant Biogen would load up attendees with gift bags as soon as they signed in at the door. To ensure the proper "pep rally" experience, Defendant Biogen usually employed a third-party event marketing company that orchestrated all of the logistics of the event, including music production, slide show projection, and food selection.

57. All of the PEPs followed a similar script. The PEP rally would begin with the attendees enjoying a nice sit-down lunch or dinner. After the meal was served, a high-prescribing physician from the Speakers Bureau would explain the benefits of Avonex and Tysabri by falsely comparing them to superior competitor drugs, all while neglecting to detail their safety concerns. Then, a nurse would talk about how to cope with a family member who has MS, for many of the

attendees brought family members to the event. The PEP rally would end with an inspirational story from an MS patient, who was paid to describe how Avonex or Tysabri changed his or her life. Speakers usually spoke from Defendant Biogen-supplied slides, and they were paid handsomely, with physician and nurse speakers making up to $2,500 and patient advocates receiving at least $500.

Paid Patient Advocates

58. ABMs were tasked with identifying Biogen patients who had inspirational stories of surviving and thriving on Avonex or Tysabri. If a patient was selected, the ABM would take the person out to an extravagant dinner and explain how she or he could earn thousands of dollars a year as a paid Patient Advocate. These Advocates traveled the country, speaking at dozens of PEPs, earning upwards of $500–$1,000 per event, plus all travel and food expenses. If the Advocates were especially effective, Defendant Biogen would promote them to Regional Patient Advocates, where they could earn even more money. The one caveat, of course, was that the patients had to promote the benefits of Avonex or Tysabri.

59. Defendants recruited Patient Advocates who were athletic, vibrant, and inspirational, with the hopes that they could drown out the FDA's grave concerns about patient safety with seemingly healthy and strong patients. The Patient Advocates were paraded in front of potential, current, and former patients, in everything from full-color magazine promos to hundreds of PEP rallies. In Relator's region, select Tysabri patients were recruited as Patient Advocates, earning thousands of dollars as the pitch men and women for Defendants' products.

Paid Patient Mentors

60. In addition to Patient Advocates, Defendants shelled out millions of dollars a year to Patient Mentors, who were MS patients using Avonex and Tysabri. If the patients were not a suitable face for the Defendants, the patients could still be the voice for the Defendants' products as Patient Mentors, where they earn up to $300/patient phone call. In either position, the Defendants' goal was to line the pockets of current patients and to blind potential patients about the serious risks and efficacy concerns associated with their products. Defendants would match the Mentors with potential, current, and former Biogen patients, who had expressed an interest in connecting with someone using Avonex or Tysabri. Moreover, after each PEP event, Defendants would personalize the follow-up discussion by matching each attendee with a Patient Mentor. When discussing Tysabri, Patient Mentors were specifically directed to talk up their personal stories and to dispel the "myth" that a high percentage of patients were killed each year using the product. For each phone call, Patient Mentors received up to $300.

61. Patient Mentors also received additional funds for moderating live local meetings of MS Patients. Defendants would organize all of the logistics of the meetings, including securing the venue and inviting the attendees, while the Patient Mentor steered the conversation to tout the benefits of Biogen's products. Patient Mentors would receive upwards of $300–$500 per meeting. As with the "PEP" rallies, Defendants used the local meetings to peddle its products, to push the benefits of various "patient services," and to introduce patients to known prescribers of Biogen products, and all with the goal of inducing patient usage and to glean personal information from the MS patients.

Return on Investment

Defendants tracked the number of additional patients it secured and retained because of its patient programs. In late November 2010, Sandra Welch, Biogen's National Manager of Patient Services, announced to the sales force that Biogen's aggressive patient marketing and patient services program had driven patient retention from 40% to over 60% in only five years. Welch further stressed that while Biogen had "invested" over $500 million in five years in paying patients and funding patient programs, the revenue generated from these initiatives well exceeded $1 billion, netting over $100 million in each of the last five years.

KICKBACKS TO HEALTH CARE PROVIDERS

62. Defendants sold hundreds of millions of dollars worth of Avonex and Tysabri because they also paid kickbacks to health care providers. Defendants cornered the MS therapy market by promising and supplying high-prescribing MS specialists with substantial cash payments and steady streams of MS patients. Defendants designed and implemented various programs utilized by its sales force to induce providers to use its MS products, Avonex and Tysabri.

Speakers Bureau

63. Defendants devised a program to track all of the MS prescription numbers in the country by prescribing physician. This level of specificity permitted Defendants to hyper-target its speaker recruitment efforts to the most prolific MS treatment prescribers, including those prescribing competitor products. Indeed, once management identified high-prescribers of

competitor products, "ABM Alerts" were sent out to the sales force, with directives to entice the physician to join the Biogen Speakers Bureau.

64. Most speakers were selected based on their prescription potential, rather than their true credentials. For especially prolific prescribers, senior management would fly across the country and join the ABM in pitching the monetary benefits of the Biogen Speakers Bureau.

65. Inasmuch as nurses were oftentimes the ultimate gatekeepers to the physicians' offices, Defendants mounted an orchestrated campaign to curry the favor of the nursing staffs. ABMs were directed to identify the gate-keeping support staff members who were most susceptible to Biogen kickbacks. As a result, the Speakers Bureau was loaded with nurses and nurse practitioners, who received thousands of dollars and all-expense-paid trips to regular "speaker training sessions."

66. Generally, the speaker programs were set up by the field. Physicians who were writing the product would get programs set up for them. Those who did not use as much product would not be used, even though they had the same (or greater) training and qualifications to speak.

67. Biogen issued speaker training participant agreements and registration forms to targeted physicians and nurses. They would be registered and trained, with a speaker profile filled out for each. ABMs crafted speaker profiles with the goal of obtaining as many paid speaking engagements as possible for the providers in their region.

68. Speaker training sessions were held in large cities such as Chicago, with the attendees flying in for an evening reception, followed by a one-half day training the next

morning. The attendees were wined and dined, and all of their travel expenses were paid for by Defendants.

69. Defendants supplied slide decks to all of the speakers. However, speakers regularly added slides to the presentation or provided their own slide decks, with full knowledge of the Biogen management in attendance.

70. After they were sufficiently trained, the nurses would then receive $500–$1,000 each time they participated in Defendant-orchestrated events, which ranged from individual training sessions with other nurses, to speaking engagements in front of hundreds of MS patients.

71. Speakers were paid, even when no attendees showed up for the event. In fact, sometimes speaker programs were limited to a single physician office or even to a single provider. Indeed, most of the events were sparsely attended, unless Defendants provided all-expense-paid trips for the attendees.

72. Defendants constantly monitored the prescription levels of the providers in its Speakers Bureau. If an ABM noticed that prescription levels were dipping below previous numbers, ABMs were directed to discuss the downward trend with the offending provider. To assist in this monitoring effort, Defendants tracked prescription numbers weekly by physician, and compared the prescription rates with year-to-date numbers from the previous year. Providers who did not prescribe would not be used.

73. Very few physicians would (without inducements) write prescriptions for Tysabri or Avonex, because of the grave patient safety problems with Tysabri and the serious efficacy concerns with Avonex, particularly when compared to competitor products. Relator believes that

all of the top twenty Biogen script-writers were on the Speakers Bureau. Avonex and Tysabri are, plain and simple, nothing more than "pay to play" products.

74. Defendants required speakers to be prescribing products in adequate numbers. If they were not, Relator and his colleagues were required to "review the numbers" with the physicians by showing the "discrepancy" between current prescription numbers and earlier levels. The message was clear that the physicians would not receive future speaking engagements and invites to advisory board meetings unless they increased their prescriptions to acceptable levels.

75. Physician attendance at Defendants' speaker events was sparse, at best. Relator estimates that about 60% of the events had 1-2 physicians, and most of the attendees were support staff. Those present would typically be the physician-speaker's nurse or wife, and the physician was paid even if he was forced to talk to the wall. Moreover, there was no oversight making sure that the speaker actually presented the information, much less that the speaker used the Defendant-supplied slide decks.

76. The top prescribing doctors in each region received tens of thousands of dollars every quarter from Defendants. A steady agenda of PEP rallies, physician speaking engagements, and advisory board meetings filled up their calendars and their bank accounts. Additionally, their nursing staffs were showered with cash for holding short training sessions, and for giving brief talks at local PEP events. All of these events were geared to parade known prescribers in front of MS patients, thus rewarding loyal prescribers with growing streams of MS patients.

77. Biogen also regularly held lavish wine-and-dine events for potential prescribers, often in conjunction with speaker programs. Indeed, ABMs were given a seemingly unending budget for entertainment, as long as the event included a targeted high-prescriber.

78. If targeted providers were on the fence about joining the Speakers Bureau, ABMs could offer to shepherd grant requests through the Defendants' approval process. Oftentimes, Defendants offered to cover the tab for research that had little to nothing to do with its product line, just to influence the provider's prescribing habits.

79. Members of the speakers bureau were regularly invited to attend other Biogen events throughout the country, including "Roundtable Discussions," "Advisory Boards," "Patient Education Programs," and Webcasts. The exact amount of "honoraria" paid to each speaker varied, based on the monetary demands of the provider. Typically, members received $2,000–$4,500 for a speaking engagement, or for attending a one-day advisory board meeting.

OFF-LABEL PROMOTION

Illegal Promotion for Extended Therapy

80. Biogen has inflated its sales by at least 30%, in the years 2007 to present, by devising a multifaceted campaign designed to keep patients on Tysabri well beyond its indicated time period.

81. Sales have increased each year, with total U.S. sales in 2010 at approximately $600 million. Indeed, Defendants increased utilization by misleading physicians and patients about the grave risks associated with prolonged Tysabri usage. The grave risks are succinctly set

forth on the boxed warning on its FDA-approved label: "TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability . . . . The relationship between the risk of PML and the duration of treatment is unknown, but most cases of PML were in patients who received more than one year of treatment."

82. This boxed warning was placed on the package label when Tysabri came back onto the market in 2006 under a risk-management program (after being withdrawn due to PML concerns). Since that time, Biogen has been publicly updating the new case counts of PML. As of early March 2011, confirmed infections rose to 102, including 21 deaths.

83. A "2010 Avonex Territory Business Strategy" identifies discontinuing Tysabri due to safety concerns (internally referred to as "Tysabri drug holiday") as a "threat" to Tysabri sales. Defendants countered this "threat" by orchestrating a campaign to encourage prolonged Tysabri usage. This messaging is evident in the training materials and talking points supplied to its sales representatives.

84. In the sales training, Biogen directed ABMs to state that there was no evidence that discontinuation of Tysabri treatment was "safer" than continued usage. However, as the boxed warning makes clear, the chance of being killed or seriously disabled by PML steadily increases over time, particularly in patients using Tysabri past the one-year point.

85. Notably, this sales training comes on the heels of a March 2010 FDA Warning Letter, in which the agency raises concerns that Biogen was using a promotional webcast to "minimize" the risks associated with prolonged Tysabri usage.

86. Biogen has amplified the voice of its sales force by leveraging social websites. Perhaps the most egregious example is seen on Youtube, where Biogen mouths its message through paid Patient Advocates, seemingly to avoid fully disclosing its products' grave safety risks.

87. The most obvious example involves Patient Advocate Lauren Parrott, who, as of June 9, 2011, had posted 91 Youtube videos, many singing the benefits of her extended Tysabri usage. In a recent video, Ms. Parrott reads from a script as she parrots the Biogen ABM talking points against "Tysabri drug holidays." For example, she argues that there is no proof that taking patients off Tysabri for a period time is safer than remaining on the drug. Ms. Parrott further states that some people have a "hypothesis that there is a cumulative risk for developing PML while on Tysabri." Of course, this "hypothesis" comes from Tysabri's boxed warning.

88. In another particularly alarming (and scripted by Biogen) video, Ms. Parrott shares that she has tested positive for the JC Virus, and, in turn, potentially has a higher likelihood of being inflicted with PML. When her doctor recommended terminating her Tysabri treatment, Ms. Parrott says that she has decided to find a new doctor who would permit her to continue her Tysabri treatment.

89. Similar misleading messages were apparently echoed in physicians' offices and at physician speaking engagements across the country.

90. Defendants utilized a high-tech online patient portal, www.msactivesource.com, to further promote staying on Tysabri past one year. This web presence closely mirrors the various marketing schemes employed by Defendant at the live events. While Defendants' names

only appear in small print at the bottom of the homepage, the site blatantly promotes Tysabri and Avonex to MS patients.

91. Moreover, Defendants invite visitors to "Create a Profile," so they can connect with other MS patients and access "helpful online tools and information." Defendants also state that registrants can use the patient portal to "find a Mentor who understands your experience" and to "find MS-related programs."

92. Notably, even if an MS patient does not "Create a Profile," they can still use msactivesource.com to register for one of the hundreds of PEP events scheduled throughout the country.

93. Defendants entered the attendees into their patient database, and paid Patient Mentors followed up with each of the attendees, dispelling any myths about patient safety concerns. For years to come, these attendees will receive a steady barrage of phone calls, mailers, and emails, all in an attempt to keep the patient on Tysabri, in order to secure additional sales.

94. Defendant Biogen also supplemented the sales force with an army of "Case Managers" and so-called "Therapy Support Coordinators," who were trained to "use behavioral science, motivational interviewing and patient risk ratings" to convince patients to remain on Biogen products. Biogen devised these and other tactics in a subversive effort to encourage patients to remain on or return to Tysabri, even when the patients' physicians have decided to suspend the patients' treatment.

Illegal Promotion for Non-Relapsing Forms of MS

95. Defendants promoted Tysabri and Avonex to be used in non-relapsing forms of MS, including progressive and secondary progressive MS.

Illegal Promotion for Pediatric Population

96. Defendants promoted Tysabri & Avonex for children under the age of 18, yet the competitors did not. Defendants have been marketing Avonex and Tysabri to pediatric patients, although they are not FDA-approved for any use in the pediatric population.

97. None of the currently available medications for MS have been FDA-approved for minors, as none have been tested in large studies in the pediatric age group. Dosing schedules vary, and the specific dose of each medication at different times in childhood is unclear.

98. At all material times, including currently, the package labels themselves acknowledge the following:

> Avonex - 2/2007
> **Pediatric**
> Safety and effectiveness of AVONEX® in pediatric patients below the age of 18 years have not been evaluated.

> Tysabri - 7/2010
> **Pediatric**
> Safety and effectiveness of TYSABRI in pediatric patients with multiple sclerosis or Crohn's disease below the age of 18 years have not been established. TYSABRI is not indicated for use in pediatric patients.

99. Even though it was not approved for pediatric use: (a) Defendants used their sales representatives to detail pediatric neurologists; misrepresented the safety and effectiveness of

Avonex and Tysabri for pediatric use; and made extensive payments and gifts to induce clinicians to prescribe the drugs for pediatric uses; and (b) Defendants had thousands of promotional sales calls or "details" with pediatric focus. The ABM's documented these details through "call notes." (c) Defendants' ABM Toolkit directly ties pediatricians into compensation.

100. Many of the sales calls were made at the following network of six Pediatric MS Centers of Excellence:

- Center for Pediatric-Onset Demyelinating Disease at the Children's Hospital of Alabama
- UCSF Regional Pediatric MS Center, San Francisco, CA, Project director: Emmanuelle Waubant, MD
- Partners Pediatric MS Center at the Massachusetts General Hospital for Children
- Yawkey Center for Outpatient Care, Massachusetts General Hospital Boston, MA, Center director: Tanuja Chitnis, MD
- Mayo Clinic Pediatric MS Center, Rochester, MN, Center directors: Nancy L. Kuntz, MD & Moses Rodriguez, MD
- Pediatric MS Center of the Jacobs Neurological Institute, Buffalo, NY, Center director: Bianca Weinstock-Guttman, MD
- National Pediatric MS Center at Stony Brook University Hospital, Stony Brook University, Stony Brook, NY, Center director: Lauren Krupp, MD

101. Defendants were well aware that its sales force was marketing Tysabri and Avonex for off-label use, as they were directed to do so.

102. In order to successfully carry out the off-label promotions, Defendants conducted national sales meetings, regional and district meetings, designed specifically for the purpose of training representatives on off-label sales and marketing practices.

103. Uniform and widespread tactics used by Defendants to promote off-label, in conjunction with kickbacks, also included hiding behind "CME" Speaker Programs via

physicians and other health care providers to promote off-label usage. These programs were controlled and promoted by Defendants.

Claims Submitted to Government Healthcare Programs for Off-label Uses Were Not Covered

104. In the Medicaid Program, states will not receive FFP ("Federal Financial Participation") if a drug, as prescribed, is not for a medically acceptable use. FFP is available to states only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). As a result, states' own laws and pharmacy regulations require that drugs must be used for a medically accepted use and therefore fit the definition of a covered outpatient drug. "Covered outpatient drugs" do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* § 1396r-8(k)(3). A medically accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" ("FDCA") or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. *Id.* § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(I) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System. The compendia will hereinafter be referred to collectively as "the Drug Compendia."

Medicare

105. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e - 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A

only if they are administered on an inpatient basis in a hospital or similar setting, and are "reasonable and necessary."

106. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting, and that are "reasonable and necessary." 42 U.S.C. § 1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. § 405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. § 1395k(a); 42 U.S.C. § 1395x(s)(2); 42 C.F.R. § 405.517.

107. With the passage of the Balanced Budget Act of 1997, Medicare beneficiaries were given the option to receive their Medicare benefits through private health insurance plans, instead of through the original Medicare plan (Parts A and B). These programs were known as "Medicare+Choice" or "Part C" plans. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, "Medicare+Choice" plans were made more attractive to Medicare beneficiaries by the addition of prescription drug coverage and became known as "Medicare Advantage" (MA) plans. Medicare pays the private health plan a capitated rate, or a set amount, every month for each member. Members typically also pay a monthly premium in addition to the Medicare Part B premium to cover items not covered by traditional Medicare (Parts A & B), such as prescription drugs, dental care, vision care and gym or health club memberships.[Medicare Advantage Plans that also include Part D prescription drug benefits are known as a Medicare Advantage Prescription Drug plan or a MA-PD.

108. The Medicare program Part D drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k).

109. The off-label uses discussed herein are not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted as safe and effective" or "reasonable and necessary" for such uses. Claims for such off-label uses were therefore not covered by Medicare.

110. Defendants were aware that the natural and probable consequence of its promotion of off-label uses described herein, was that health care providers would submit claims for payment to Government Healthcare Programs for the off-label uses.

111. Notwithstanding this knowledge, Defendants illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted these off-label uses. Defendants were aware that its illegal promotion did in fact result in false claims to these and other Government payors for the off-label uses. Defendants were aware that its promotion activities were a substantial factor in producing the claims.

112. When pharmacies, physicians and other health care providers submitted claims based upon a physician's prescription for off-label uses, the claims they submitted were false because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I), (Medicaid) not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective" or "reasonable and necessary" (Medicare) and not covered by other Government Healthcare Programs (*See, e.g.,*

TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002)).

113. False claims to these Government Healthcare Programs for off-label prescribing were the direct and proximate result of unlawful off-label marketing efforts by Defendants. Defendants caused the submission of these claims.

114. The decision-making of the physician, that important element in Government Healthcare Program coverage policy was completely undermined by the unlawful marketing of Defendants. The physicians prescribing Defendants' drugs did not necessarily do so because they believed, based on their review of peer-reviewed medical literature, or discussions with their colleagues, that the drugs would help their patients; rather the drugs were often prescribed because the physicians were actively pursued by Defendants with kickbacks.

COUNT I
FALSE CLAIMS ACT

115. Relator realleges and incorporates by reference paragraphs 1 through 100 as though fully set forth herein.

116. This is a claim by Relator, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. In the District of Massachusetts and elsewhere throughout the United States, Defendants have knowingly and willfully violated the False Claims Act by causing false claims to be submitted.

117. Defendants have knowingly caused pharmacies and other health care providers to submit Pharmacy Claim Forms, CMS-1500 Claim Forms, and other Claim Forms for payment, knowing that such false claims would be submitted to state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for prescriptions induced by kickbacks and/or for non-covered uses and therefore false claims. By virtue of the acts described in this Complaint, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. §3729(a)(1) and 31 U.S.C. §3729(a)(2).

118. Defendants have violated 31 U.S.C. §3729(a)(2) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, were paid for in compliance with federal law. States submitted false claims to the United States Government because when the subject drugs were prescribed off-label, they were not prescribed for medically accepted indications, yet states sought reimbursement from the United States Government for all such expenditures.

119. Defendants caused false claims to be submitted, resulting in Government Healthcare Program reimbursement to health care providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. § 3729 *et. seq.* and the Anti-Kickback Act 42 U.S.C. § 1320a-7b(b)(2)(A).

120. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

121. WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendants caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT II
CALIFORNIA FALSE CLAIMS ACT

122. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

123. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 et seq.

124. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> ...
>
> (8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

125. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

126. Defendants violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the conduct described herein.

127. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

128. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

129. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

130. Had the State of California known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

131. As a result of Defendants' violation of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

132. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

133. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT III
COLORADO MEDICAL ASSISTANCE ACT

134. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

135. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq*.

136. Colo. Rev. Stat § 25.5-4-305 provides that it is unlawful to:

(a) Intentionally or with reckless disregard make or cause to be made any false representation of a material fact in connection with a claim;

(b) Intentionally or with reckless disregard present or cause to be presented to the state department a false claim for payment or approval;

> (c) Intentionally or with reckless disregard present or cause to be presented any cost document required by the medical assistance program that the person knows contains a false material statement…

137. In addition, the payment or receipt of bribes or kickbacks is prohibited under the Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-305 (1)(e).

138. Defendants furthermore violated Colorado Medical Assistance Act, Colo. Rev. Stat. § 25.5-4-305 *et seq*. and knowingly caused false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq*. and Colo. Rev. Stat. § 25.5-4-305(1)(e) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

139. The State of Colorado, by and through the Colorado Medical Assistance Act and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

140. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Colorado in connection with Defendants' conduct. Compliance with applicable Colorado statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Colorado.

141. Had the State of Colorado known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the

subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

142. As a result of Defendants' violation of Colo. Rev. Stat § 25.5-4-305, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

143. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 *et seq.* on behalf of himself and the State of Colorado.

144. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Colorado in the operation of its Medicaid program.

WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the State of Colorado:

(1) Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Colorado;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IV
CONNECTICUT FALSE CLAIMS ACT

145. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

146. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Public Act No. 09-5 *et seq.*, signed by the Governor on October 5, 2009.

147. Conn. Public Act No. 09-5 § 2(a) provides that no person shall:

> (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under medical assistance programs administrated by the Department of Social Services;
> (2) Knowingly make, or cause to be made or used a false record or statement to secure the payment by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;
> (3) Conspire to defraud the state by securing the allowance of payment of a false claim under medical assistance programs administered by the Department of Social Services.

148. In addition, the payment or receipt of bribes or kickbacks is prohibited under Connecticut False Claims Act, Public Act No. 09-5 § 16(a).

149. Defendants furthermore violated Conn. Public Act No. 09-5 § 2(a) and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Conn. Public Act No. 09-5 § 2(a) and § 16(a) and by virtue of the fact that none of the

claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

150. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

151. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Connecticut.

152. Had the State of Connecticut known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

153. As a result of Defendants' violation of Conn. Public Act No. 09-5 § 2(a), the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

154. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Connecticut False Claims Act, Public Act No. 09-5 *et seq*. on behalf of himself and the State of Connecticut.

155. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Connecticut in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Connecticut:

(1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Connecticut;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Public Act No. 09-5 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT V
DELAWARE FALSE CLAIMS AND REPORTING ACT

156. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

157. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

158. 6 Del. C. § 1201(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

159. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

160. Defendants violated 31 Del. C. § 1005 by engaging in the conduct described herein.

161. Defendants furthermore violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

162. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

163. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with

Defendants' conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

164. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

165. As a result of Defendants' violation of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

166. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

167. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VI
FLORIDA FALSE CLAIMS ACT

168. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

169. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

170. Fla. Stat. § 68.082(2) provides liability for any person who-

> (a) knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

171. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;

* * *

> (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

172. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

173. Defendants violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

174. Defendants furthermore violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

175. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

176. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

177. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

178. As a result of Defendants' violation of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

179. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

180. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Florida
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of' law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VII
GEORGIA FALSE MEDICAID CLAIMS ACT

181. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

182. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) *et seq.*

183. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

184. Defendants violated O.C.G.A. § 49-4-168 *et seq.* by engaging in the conduct described herein.

185. Defendants furthermore violated O.C.G.A. § 49-4-168 and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

186. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

187. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

188. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

189. As a result of Defendants' violation of O.C.G.A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

190. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of himself and the State of Georgia.

191. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VIII
HAWAII FALSE CLAIMS ACT

192. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

193. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq*.

194. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

195. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

196. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

197. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

198. Had the State of Hawaii known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

199. As a result of Defendants' violation of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

200. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

201. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

202. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

203. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175 *et seq.*

204. 740 Ill. Comp. Stat. 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

205. In addition, 305 Ill. Comp. Stat. 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

206. Defendants violated 305 Ill. Comp. Stat. 5/8A-3(b) by engaging in the conduct described herein.

207. Defendants furthermore violated 740 Ill. Comp. Stat. 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

208. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

209. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

210. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

211. As a result of Defendants' violation of 740 Ill. Comp. Stat. 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

212. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 Ill Comp. Stat. 175/3(b) on behalf of himself and the State of Illinois.

213. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 Ill. Comp. Stat.175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

214. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

215. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq.* provides:

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)...

216. In addition, Indiana Code 5-11-5.5 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or

covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Indiana Medicaid program.

217. Defendants violated the Indiana Code 5-11-5.5 *et seq.* by engaging in the conduct described herein.

218. Defendants furthermore violated Indiana Code 5-11-5.5 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Indiana Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

219. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

220. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

221. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

222. As a result of Defendants' violation of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

223. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of himself and the State of Indiana.

224. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A Civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the State of Indiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

225. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

226. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46: 437.1 *et seq.*

227. La. Rev. Stat. 46: 438.3 provides-

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

228. In addition, La. Rev. Stat. 46: 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the Louisiana medical assistance programs.

229. Defendants violated La. Rev. Stat. 46: 438.2(A) by engaging in the conduct described herein.

230. Defendants furthermore violated La. Rev. Stat. 46: 438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. 456: 438.2(A), and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

231. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

232. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

233. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

234. As a result of Defendants' violation of La. Rev. Stat. 46: 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

235. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. 46: 439.1(A) on behalf of himself and the State of Louisiana.

236. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII
MARYLAND FALSE HEALTH CLAIMS ACT OF 2010

237. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

238. This is a *qui tam* action brought by Relator on behalf of the State of Maryland to recover treble damages and civil penalties under the Md. Health General Code Subtitle 6 §§ 2-601 et seq.

239. Md. Health General Code Subtitle 6 § 2-602 provides in pertinent part:

> (a) A person may not:
>
> (1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
> (2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim ...
> ***
> (9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

240. Defendants furthermore violated Md. Health General Code Subtitle 6 § 2-602 et seq. and knowingly caused false claims to be made, used and presented to the State of Maryland by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

241. The State of Maryland, by and through the Maryland Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

242. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Maryland in connection with Defendants' conduct. Compliance with applicable Maryland statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Maryland.

243. As a result of Defendants' violation of Md. Health General Code Subtitle 6 § 2-602 et seq., the State of Maryland has been damaged in an amount far in excess of millions of dollars exclusive of interest.

244. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Md. Health General Code Subtitle 6 § 2-602 et seq. on behalf of himself and the State of Maryland.

245. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Maryland:

(1) Three times the amount of damages that the State of Maryland sustains as a result of Defendants' conduct;
(2) A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State Maryland;
(3) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Md. Health General Code Subtitle 6 § 2-602 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII
MICHIGAN MEDICAID FALSE CLAIMS ACT

246. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

247. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

> 400.603 provides liability in pertinent part as follows:
> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits;
> (2)A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit...

248. In addition, MI ST Ch. 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Michigan Medicaid program.

249. Defendants violated MI ST Ch. 400.603 *et seq.* by engaging in the conduct described herein.

250. Defendants furthermore violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

251. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

252. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Michigan.

253. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

254. As a result of Defendants' violation of MI ST Ch. 400.603 *et seq.* the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

255. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to MI ST Ch. 400.603 *et seq.* on behalf of himself and the State of Michigan.

256. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;
(2) A civil penalty equal to the full amount received for each false claim which Defendants caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
MINNESOTA FALSE CLAIMS ACT

257. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 102 above as if fully set forth herein.

258. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. § 15C.01, *et seq.*

259. Minn. Stat. § 15C.02 provides civil liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;

(2) knowingly makes or uses, or causes to be made or used, a false record or

> statement to get a false or fraudulent claim paid or approved by the state or a political subdivision;
>
> (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim;...

260. In addition, Nev. Rev. Stat. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

261. In addition, the State of Minnesota prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Minnesota False Claims Act. Defendants violated Minn. Stat. § 15C.01, *et seq.* by engaging in the conduct described herein.

262. Defendants furthermore violated, Minn. Stat. § 15C.01, *et seq.* and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

263. The State of Minnesota, by and through the Minnesota False Claims Act program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

264. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Minnesota.

265. Had the State of Minnesota known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

266. As a result of Defendants' violation of Minn. Stat. § 15C.01, *et seq.* the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

267. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Minn. Stat. § 15C.01, *et seq.* on behalf of himself and the State of Minnesota.

268. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Minnesota:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;
(2) A civil penalty equal to the full amount received for each false claim which Defendants caused to be presented to the State of Minnesota;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn. Stat. § 15C.01, *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
NEVADA FALSE CLAIMS ACT

269. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

270. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010, *et. seq.*

271. Nev. Rev. Stat. § 357.040(1) provides liability for any person who-

> (a) knowingly presents or causes to be presented a false claim for payment or approval;
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

272. In addition, Nev. Rev. Stat. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

273. Defendants violated Nev. Rev. Stat. § 422.560 by engaging in the conduct described herein.

274. Defendants furthermore violated Nev. Rev. Stat.§ 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and Nev. Rev. Stat. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

275. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

276. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

277. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the

subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

278. As a result of Defendants' violation of Nev. Rev. Stat. § 357.040(1) the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

279. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of himself and the State of Nevada.

280. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to Nev. Rev. Stat. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT

281. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

282. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev.Stat. Ann§167:61-b *et seq.* provides:

> 1. Any person shall be liable who...
>
> (a) knowingly presents, or causes to be presented, to an officer or employee of the department a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
> (f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim

283. In addition, N.H. Rev.Stat. Ann. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Hampshire Medicaid program.

284. Defendants violated the N.H. Rev.Stat. Ann by engaging in the conduct described herein.

285. Defendants furthermore violated N.H. Rev.Stat. Ann. §167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by its

deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New Hampshire Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

286. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

287. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' conduct. Compliance with applicable New Hampshire statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Hampshire.

288. Had the State of New Hampshire known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

289. As a result of Defendants' violation of N.H. Rev.Stat. Ann. §167:61-b *et seq.*, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

290. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b *et seq.* on behalf of himself and the State of New Hampshire.

291. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New Hampshire:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII
NEW JERSEY FALSE CLAIMS ACT

292. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

293. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.* (2008) *et seq.*

294. N.J. Stat. § 2A:32C-3 provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to an employee, officer, or agent of the State or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

295. In addition, Section 17 of P.L. 1968, c.413 (C.30:4D-17) of the New Jersey False Claims Act prohibits the solicitation, offer or receipt of any remuneration, including any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program.

296. Defendants violated Section 17 of P.L. 1968, c.413 (C.30:4D-17) by engaging in the conduct described herein.

297. Defendants furthermore violated N.J. Stat. § 2A:32C-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New Jersey False Claims Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

298. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

299. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.

300. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

301. As a result of Defendants' violation of N.J. Stat. § 2A:32C-1 *et seq.*, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

302. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 *et seq.* on behalf of himself and the State of New Jersey.

303. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 *et seq.*) which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

304. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

305. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act N.M. Stat. Ann§§ 27-14-1 *et seq.*

306. Section 4 provides liability in pertinent part as follows:

A person ...shall be liable...if the person:

> A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
> B. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;
> D. conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent;

307. It is also brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 *et seq*. provides liablity in pertinent part as follows:

> § 44-9-3(A) A person shall not:
>
> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim;

308. In addition, N.M. Stat. Ann§§ 30-44-7 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Mexico Medicaid program.

309. Defendants violated N.M. Stat. Ann§§ 30-44-7 et seq by engaging in the conduct described herein.

310. Defendants furthermore violated, N.M. Stat. Ann§§ 27-14-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

311. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

312. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.

313. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

314. As a result of Defendants' violation of N.M. Stat. Ann§§ 27-14-1 *et seq.* the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

315. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* on behalf of himself and the State of New Mexico.

316. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
NEW YORK FALSE CLAIMS ACT

317. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

318. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII

319. Section 189 provides liability for any person who:

> 1.(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
> 1. (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
> 1. (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

320. In addition, the New York State Consolidated Laws prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New York Medicaid program.

321. Defendants violated the New York State Consolidated Laws by engaging in the conduct described herein.

322. Defendants furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, including the FDCA, federal

Anti-Kickback Act, and the New York Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

323. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

324. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' conduct. Compliance with applicable New York statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New York.

325. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

326. As a result of Defendants' violation of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

327. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of himself and the State of New York.

328. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
NORTH CAROLINA FALSE CLAIMS ACT

329. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

330. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

331. N.C. Gen. Stat. § 1-607(a) provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

332. In addition, North Carolina Statutes prohibit the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the North Carolina Medicaid program.

333. Defendants violated N.C. Gen. Stat. § 1-607(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and the North Carolina False Claims Act N.C. Gen. Stat. § 1-605 *et seq.*, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

334. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

335. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express

condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

336. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

337. As a result of Defendants' violation of N.C. Gen. Stat. § 1-605 *et seq.*, and its anti kickback statutes, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

338. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C. Gen. Stat. § 1-605(b) on behalf of himself and the State of North Carolina.

339. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of North Carolina:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of North Carolina;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-605 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI
OKLAHOMA MEDICAID FALSE CLAIMS ACT

340. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

341. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq.*

342. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

343. In addition, 56 Okl. St. § 1005 (2008) of the Oklahoma Medicaid Program Integrity Act prohibits the solicitation or receipt of any benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

344. Defendants violated 56 Okl. St. § 1005 *et seq.* by engaging in the conduct described herein.

345. Defendants furthermore violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Oklahoma Medicaid Program Integrity Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

346. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

347. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

348. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

349. As a result of Defendants' violation of 63 Okl. St. § 5053.1 *et seq.*, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

350. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 *et seq.* on behalf of himself and the State of Oklahoma.

351. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 *et seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII
RHODE ISLAND STATE FALSE CLAIMS ACT

352. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

353. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I.Gen. Laws § 9-1.1-1 (2008) *et seq.*

354. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

355. In addition, R.I. Gen. Laws § 40-8.2-3(2)(i) prohibits the solicitation, receipt, offer or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Rhode Island Medicaid program.

356. Defendants violated R.I. Gen. Laws § 40-8.2-3 *et seq.* by engaging in the conduct described herein.

357. Defendants furthermore violated R.I.Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Rhode Island General Laws and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

358. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

359. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

360. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

361. As a result of Defendants' violation of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

362. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 *et seq.* on behalf of himself and the State of Rhode Island.

363. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
TENNESSEE MEDICAID FALSE CLAIMS ACT

364. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

365. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq*.

366. § 71-5-182(a)(1) provides liability for any person who-

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

367. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

368. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

369. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

370. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

371. As a result of Defendants' violation of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

372. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

373. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
TEXAS MEDICAID FRAUD PREVENTION LAW

374. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

375. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001 *et seq.*

376. Tex. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit

(2) knowingly or intentionally concealing or failing to disclose an event:
(A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.

(i) the person, or
(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
(B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
(B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

377. Defendants violated Tex. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

378. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

379. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

380. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

381. As a result of Defendants' violation of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

382. Defendants did not, within 30 days after it first obtained information as to such violation, furnish such information to officials of the State responsible for investigating false claims violation, did not otherwise fully cooperate with any investigation of the violation, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

383. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

384. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 or more than $15,000 pursuant to Tex. Hum.. Res. Code § 36.025(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

385. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

386. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.*

387. Wis. Stat. § 20.931(2) provides liability for any person who:

> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
> (c) conspires to defraud this State by obtaining allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
> (g) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

388. In addition, Wis. Stat. § 49.49(2) of the Wisconsin Public Assistance Code prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Wisconsin Medicaid program.

389. Defendants violated Wis. Stat. § 49.49(2) by engaging in the conduct described herein.

390. Defendants furthermore violated Wis. Stat. § 20.931 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Wisconsin Public Assistance Code and Kickback statute, and by virtue of the fact that

none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

391. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

392. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' conduct. Compliance with applicable Wisconsin statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Wisconsin.

393. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

394. As a result of Defendants' violation of Wis. Stat. § 20.931 *et seq.* , the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

395. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 *et seq.* on behalf of himself and the State of Wisconsin.

396. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
MASSACHUSETTS FALSE CLAIMS ACT

397. Plaintiff repeat and reallege each allegation contained in paragraphs 1 through 139 above as if fully set forth herein.

398. This is a qui tam action brought by Relators on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Chap. 12 § 5(A) et seq.

399. Mass. Gen. Laws Chap. 12 § 5B provides liability for any person who-

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or ...
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> ***
> (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim shall be liable to the commonwealth or political subdivision.

400. In addition, Mass. Gen. Laws Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

401. Defendants violated Mass. Gen. Laws Chap. 118E § 41 by engaging in the conduct described herein.

402. Defendants furthermore violated Mass. Gen. Laws Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

403. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

404. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief: also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

405. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

406. As a result of Defendants' violation of Mass. Gen. Laws Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

407. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mass. Gen. Laws Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

408. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Defendants:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relators:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Chap. 12, § 5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relators incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

409. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

410. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Va. Code Ann. § 8.01-216.3a provides liability for any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

411. In addition, Va. Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Virginia Medicaid program.

412. Defendants violated Va. Code Ann. § 32.1-315 by engaging in the conduct described herein.

413. Defendants furthermore violated Va. Code Ann. § §8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, VA Code ANN § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

414. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

415. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy

Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

416. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

417. As a result of Defendants' violation of Va. Code Ann. §8.01-216.3(A), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

418. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.3 on behalf of himself and the Commonwealth of Virginia.

419. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Va. Code Ann. § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVIII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

420. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 100 above as if fully set forth herein.

421. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

422. D.C. Code § 2-308.14(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to: be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
> (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

423. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program, or
> (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

424. Defendants violated D.C. Code § 4-802(c) by engaging in the illegal conduct described herein.

425. Defendants furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

426. The District of Columbia, by and through the District of Columbia Medicaid program and other state healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

427. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct. Compliance with applicable D.C. statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District

of Columbia.

428. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

429. As a result of Defendants' violation of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

430. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

431. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

DATED: June 13, 2011

Respectfully submitted,

By: _____

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